

CALIFORNIA DEPARTMENT OF THE YOUTH AUTHORITY RESEARCH PROJECT APPROVAL GUIDELINES

I. PURPOSE

Purpose of the Research Project Approval Process The purpose of the California Department of the Youth Authority research project approval process is to encourage research that furthers the purposes of the Youth Authority while complying with federal and state guidelines and accepted professional and scientific ethics.

Intent of the Research Project Approval Process Through this process, the Youth Authority's intent is to: 1) protect human subjects, 2) define and ensure confidentiality, 3) articulate the roles and responsibilities of researchers and evaluators, and 4) support research projects that increase knowledge about the extent and causes of juvenile crime and delinquency, as well as the methods of prevention and correction. These guidelines are intended to supplement rather than to replace applicable state and federal laws, regulations, and policies regarding the protection of human research subjects. Prospective researchers are encouraged to contact their Institutional Review Boards for additional advice and guidance regarding their proposals.

II. DEFINITION AND SCOPE

Definition of Research Federal Policy regarding the protection of human subjects (56FR28003) defines research as: "... a systematic investigation, including research development, testing and evaluation, designed to contribute to generalizable knowledge." The California State Penal Code (PC), Section 3500, expands this definition to include data upon which such knowledge may be based, and requires that such knowledge can be corroborated by accepted scientific observation and inferences.

This definition encompasses research and evaluation conducted by Youth Authority employees, contractors, faculty at institutions of higher education, researchers with private research firms, governmental agencies, and students. Projects that involve personal interaction with youthful offenders committed to and paroled by the Youth Authority, process and evaluative projects, clinical trials of interventions, and any requests by outside researchers for access to YA wards, staff, or data are subject to this review and approval process.

Biomedical Research Except for specific exceptions, biomedical research may not be conducted on any prisoner in the State of California (PC §3502). Directives from the Secretary of the Youth and Adult Correctional Agency and the Director of the Youth Authority also prohibit the conducting of biomedical research on wards. This applies to research relating to or involving biological, medical, or physical science. The only exceptions are for research that is specifically codified in statute and approved by the Director of the Department, the Secretary of the Youth and Adult Correctional Agency, and the Governor's Office.

Behavioral Research According to PC §3505, behavioral research is limited to studies of the possible causes, effects and processes of incarceration, to studies of prisons as institutional structures, and of prisoners as incarcerated persons. Allowable studies present minimal or no risk to the subjects of the research, and no more than mere inconvenience.

Before approving behavioral research projects, PC §3515 requires the Department to determine:

- a) That the sum of the benefits to the prisoners and the value of knowledge gained outweigh the risks to the participants.
- b) That the rights and welfare of the prisoners are adequately protected, including the security of any confidential personal information.
- c) That the selection process is equitable and the rate of remuneration for participation is comparable to that received by nonprisoner volunteers in similar research.
- d) That provisions have been made to compensate any research-related injury.
- e) That research activity will be reviewed regularly.
- f) That legally effective informed consent will be obtained by adequate and appropriate methods.

III. RESEARCH PROJECT APPROVAL PROCESS

Action on proposals shall be taken within 60 days of their submission (PC §3517). Each research project involving Youth Authority wards must receive prior approval by the Director of the Youth Authority before the project can begin. The Director may delegate approval authority to the Research Project Approval Committee (RPAC) for selected projects. Any decisions delegated by the Director will be reported to the Director at least quarterly.

The Director's decision will follow completion of the Department's research project approval process. An initial review of a proposal will be conducted by the RPAC Coordinator, who is a staff person the Research Division. After the RPAC Coordinator reviews the proposal, the Chief of Research will prepare a written recommendation to the RPAC.

The RPAC will consist of the Chief of Research, who will chair the committee, and at least four other members. The members will include the Department's Chief Counsel and the Deputy Directors of the Institutions and Camps Branch, the Parole Services and Community Corrections Branch, and the Administrative Services Branch (or their designees). Depending on the topic of the research project under review, the Deputy Director of the Office of Prevention and Victim Services, the Deputy Director of the Education Services Branch, or the Chief of the Health Care Services Division may be added to the Committee. In addition, appropriately qualified personnel from any of the branches may be added to the committee at the discretion of the RPAC's Chair.

The committee will promptly review each proposal forwarded to it from the Research Division. By majority vote, the committee will make a written recommendation to the Director to approve or disapprove the project. The research project proposal, along with the recommendations and comments by the Research Division and the RPAC, will be forwarded to the Director for a final decision. The Director may waive a specific requirement established by the Department if it is found to be in the best interests of the Department and if doing so does not put wards at greater risk of identifiable adverse consequences.

The Research Division will send written notification of the Director's decision to investigators who submit research proposals.

Modifications to Approved Projects Proposed changes to any previously approved research project must be submitted to the RPAC Coordinator for additional review and approval before any changes are implemented.

Exempt Projects The following *do not* require approval through the research project approval process:

- a) Routine statistical tabulations by Youth Authority employees in the scope of their duties.
- b) Administrative program reviews conducted by Youth Authority employees.

Expedited Review Process The expedited review process will be used when investigators propose to undertake no more than the following actions:

- 1) Research projects that propose to conduct file reviews or staff interviews without any direct interaction with wards, and which involves no more than minimal risk..
- 2) Minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

Proposals that meet the criteria above are not eligible for expedited review and must be reviewed under provisions of the full research project approval process if:

- (1) Approval may commit significant Department financial, staff, or other resources to the project.
- (2) Approval raises policy issues for the Department.

Under the expedited review procedure, the RPAC chairperson, or experienced RPAC members designated by the RPAC Chairperson, may carry out the review on behalf of the RPAC. Reviewers may exercise all of the authority of the RPAC except that the reviewer(s) may not disapprove research projects. Research proposals may only be disapproved after review in accordance with the full research project approval process. Any projects or changes approved through the expedited review process will be reported quarterly by the Research Division to the RPAC members and the Director.

IV. CONTENTS OF RESEARCH PROJECT PROPOSALS

Research proposals submitted to the Youth Authority for review and approval should include the following information:

1. Project Title
2. Summary
3. Name, contact address, current affiliation, and a curriculum vitae for the principle investigator and any co-investigators.
4. Purpose and objectives of the project. For example, what issues is the research project designed to address?
5. Hypotheses to be tested.
6. A detailed description of the proposed research design and methodology. If the research design or methods are innovative or unusual, a brief justification should be included in the proposal.
7. Locations of project activity, such as data collection at Central Office, at an institution, or at a parole office.
8. Project duration, including starting and completion dates.
9. Number of subjects who will participate in the study, employees and wards, and the estimated amount of time required from each to participate.

10. Detailed estimates of the costs, staff time, and any other resources required from the Department to support the project.
11. If applicable, a signed approval by the institutional superintendent or supervising parole agent, stating that the proposed research is feasible and practical and that the necessary safeguards for staff and wards are in place.
12. A description of all risks, discomfort, and benefits to wards and staff as a result of participating in the study, along with an estimate of the probability of their occurrence.
13. A description of steps that will be taken to minimize any risks to participants.
14. A detailed description of all confidentiality provisions.
15. A description of physical and administrative procedures and practices that will:
 - (a) Ensure the security of any individually identifiable data that are being collected and maintained for the project's duration.
 - (b) Ensure the elimination of individual identifiers from research records when the research is completed.
16. A statement regarding assurances of confidentiality of identifiable research and statistical information as required by the Code of Federal Regulations 28, Part 22.
17. Drafts of relevant research materials, such as proposals, endorsements, questionnaires, interview schedules, and sample informed consent statements.
18. A description of the sponsoring agency's Institutional Review Board (IRB).
19. A copy of the Human Subjects Review protocol submitted to the IRB as well as all responses, including comments and requests for changes.
20. A copy of the written final approval from the IRB. This document should demonstrate that the IRB is aware of, and has considered, relevant federal and state laws and regulations regarding the use of human subjects in general, and specifically the use of human subjects who are incarcerated, who are minors, or who are otherwise vulnerable populations.
21. A statement regarding assurances of protection of human subjects as required by the Code of Federal Regulations 28, Part 46.

Responsibilities of the Principal Investigator The research project's principal investigator must assume responsibility for actions of any person participating in the research project, such as an associate, assistant, or subcontractor to the project. Principle investigators must provide written assurance of acceptance of this responsibility for themselves and for those persons whose actions they are responsible. The principal investigator must also adhere to the provisions of the state's Information Practice Act of the Civil Code (Section 1798 et seq.) and the Public Records Act of the Government Code (Sections 6250-6260).

Multiple Roles of Investigators Throughout the research process, the Department seeks to avoid any situations that inadvertently subordinate the rights of the participants to the personal or professional interests of the researcher. Accordingly, researchers must have no other evaluation, diagnosis, or treatment relationship with research subjects which may result in a conflict of interest or create an environment in which subjects feel compelled or otherwise coerced to participate in research activities. Caregivers who are also investigators are prohibited from recruiting their own patients. Once investigators have established a research relationship, they must exclude themselves from current or prospective treatment roles and responsibilities.

Informed Consent and Disclosure Research projects must adhere to federal and state laws and regulations regarding informed consent of imprisoned participant subjects. Informed consent must also be obtained from employees of the CYA who are subjects or respondents in research projects.

A ward in the State of California is deemed to have given informed consent when the following conditions (taken from PC §5321) are met:

- (a) Consent is given without duress, coercion, fraud, or undue influence.
- (b) Wards are informed in writing of the potential risks and benefits of the proposed research. At the same time, researchers must inform wards as to the amount of remuneration to be received for participating in the research, as well as the manner in which wards may obtain prompt treatment for any research-related injuries. This information must be provided in writing, on a form that is to be retained by the wards (PC §3522).
- (c) The participant is informed orally and in writing of each of the following in a language in which he or she is fluent:
 - (1) An explanation of the research procedures and their purposes, including identification of any experimental procedures.
 - (2) A description of all known discomfort associated with the research procedures along with any reasonably expected risks to participants.
 - (3) A disclosure of alternative biomedical or behavioral research procedures that might be advantageous for the subject.

- (4) The nature of the information sought to be gained through the research.
- (5) The expected time required for recovery following participation in a research procedure or experiment.
- (6) An offer to answer participants' questions concerning any of the research procedures.
- (7) The right to withdraw consent and to discontinue participation in the research at any time without prejudice to the subject.

In short, the consent form should be designed so that it is clear to anyone who knows the participant that he or she was clearly informed of the nature of the study, the possible risks and benefits, the fact that their participation is voluntary, and the meaning of "voluntary" for this "vulnerable" population.

Informed consent forms must be written at a fourth grade reading level or lower. Informed consent must be obtained directly from participants who are 18 years or older. For those who are under 18, informed consent can only be granted by participants' parents or guardians, or must be obtained through the courts.

Certain types of information revealed by youthful offenders participating in research projects must be disclosed to Youth Authority staff. Mandatory disclosures include allegations of child abuse, threats of harm to themselves or others, and involvement in serious criminal activity previously unreported. Notification of this requirement must be included in the informed consent form.

Copies of each signed informed consent form must be provided to staff in the Youth Authority's Research Division. The research project's principal investigator should retain original copies of each signed informed consent.

Confidentiality and Access to Research Data Section 1798 et seq. of the California Civil Code provides guidelines that must be observed before access to information for research purposes can be granted. When these requirements are met, access may be granted to:

- (a) A person who has provided the agency with advance written assurance that the information will be used solely for statistical research or reporting purposes, but only if the information to be disclosed is in a form that will not identify any individual;
- (b) The University of California or a non-profit educational institution conducting scientific research, provided the request for information includes assurances of the need for personal information, procedures for protecting the confidentiality of the information and assurances that the personal identity of the subject shall not be further disclosed in individually identifiable form.

Proponents of research projects will be required to sign a form providing written assurance that the information they obtain will be used solely for research purposes and will meet all federal and state security and confidentiality requirements.

Once a research project has been approved, any changes in the use of these data are subject to approval in accordance with the Department's research project approval process.

Researchers agree to acknowledge the California Department of the Youth Authority as the source of their data when these data, or reports based on these data, are presented or published. Unless otherwise agreed upon, these data remain the property and under the control of the CYA.

V. PROPOSAL SUBMISSIONS

Research project proponents are encouraged to discuss their research concepts and proposals with Research Division staff prior to submission. Contact the RPAC Coordinator by telephone at (916) 262-1493 or by forwarding the request via the Youth Authority's web site at http://www.cya.ca.gov/contact/info_req.html. Preliminary approval of a proposal by Research Division staff does not constitute written approval from the Director.

Submit research proposals by mail to the following address:

Research Project Approval Committee Coordinator
California Youth Authority
Research Division
4241 Williamsborough Drive, Suite 216
Sacramento, CA 95823-2088

Proposals may also be submitted electronically. Applicants may obtain the current e-mail address for the Research Project Approval Committee Coordinator via the Request for Information form on the Youth Authority URL: http://www.cya.ca.gov/contact/info_req.html.